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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/815,675	03/23/2001	James R. Matson	067062.0110	5775

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EXAMINER	
KIM, SUN U	

ART UNIT	PAPER NUMBER
1723	

DATE MAILED: 08/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/815,675	MATSON, JAMES R.
	Examiner	Art Unit
	John Kim	1723

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 July 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,7,11 and 12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,7,11 and 12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 March 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

1. The indicated allowability of claim 7 is withdrawn in view of the newly discovered reference(s) to U.S. Patent No. 5,919,444. Rejections based on the newly cited reference(s) follow.

2. Claims 1-2, 7 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,287,516 (Matson et al) in view of U.S. Patent No. 5,919,444 (hereinafter referred to as Norman, Jr.). Matson et al teach a hemofiltration method and system comprising a 100 kilo dalton to 150 kilo dalton hemofilter (102) to remove selective inflammatory mediators including cytokines, prostaglandins, TNF, IL-1 beta from blood and connected to an adsorptive device (108) having adsorbents including biological agent including anti-TNF antibody and monoclonal antibodies to remove inflammatory mediators (see figure 1; col. 5, line 17-23; col. 11, line 1 - col. 14, line 2). Claims 1-2, 7 and 11 essentially differ from the hemofiltration system and method of Matson et al in reciting the provision of therapeutic agent selected from the group consisting of allopurinol, elastase inhibitors and prostaglandin inhibitors. Norman, Jr. teaches that IL-1 and TNF as major mediators of the systemic response to diseases such as sepsis and pancreatitis and as activators of the remaining members of the cytokine cascade and activates inflammatory cytokines (see col. 4, line 40 – col. 5, line 22). Norman, Jr. further teaches that IL-1 block can be administered in combination with other drugs such as prostaglandin inhibitors (i.e., non-steroidal, anti-inflammatory drugs such as aspirin, indomethacin, ibuprofen, etc.) to inhibit IL-1 production (see col. 6, lines 34-63; col. 9, lines 27-50). It would have been obvious to a person of ordinary skill in the art to modify the hemofiltration system and method of Matson et al to provide one therapeutic agent including prostaglandins inhibitors to effectively treat inflammation caused by inflammatory mediators as suggested by Norman, Jr.

3. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Matson et al in view of Norman, Jr. and U.S. Patent No. 6,008,199 (Grinnell et al '199). Matson et al teach a hemofiltration method and system comprising a 100 kilo dalton to 150 kilo dalton hemofilter (102) to remove selective inflammatory mediators including cytokines, prostaglandins, TNF, IL-1 beta from blood and connected to an adsorptive device (108) having adsorbents including biological agent including anti-TNF antibody and monoclonal antibodies to remove inflammatory mediators (see figure 1; col. 5, line 17-23; col. 11, line 1 - col. 14, line 2). Claim 12 essentially differs from the hemofiltration method of Matson et al in reciting the provision of therapeutic agent selected from the group consisting of allopurinol, elastase inhibitors and prostaglandin inhibitors and activated protein C. Norman, Jr. teaches that IL-1 and TNF as major mediators of the systemic response to diseases such as sepsis and pancreatitis and as activators of the remaining members of the cytokine cascade and activates inflammatory cytokines (see col. 4, line 40 – col. 5, line 22). Norman, Jr. further teaches that IL-1 block can be administered in combination with other drugs such as prostaglandin inhibitors (i.e., non-steroidal, anti-inflammatory drugs such as aspirin, indomethacin, ibuprofen, etc.) to inhibit IL-1 production (see col. 6, lines 34-63; col. 9, lines 27-50). Grinnell et al '199 teach that activated protein C is used to treat sepsis caused by inflammatory mediators because of its anti-inflammatory effects through its inhibition of cytokine generation (e.g. TNF and IL-1) (see abstract; col. 1, lines 41-53). It would have been obvious to a person of ordinary skill in the art to modify the hemofiltration method of Matson et al to provide one therapeutic agent including prostaglandins inhibitors and activated protein C in blood to effectively treat inflammation caused by inflammatory mediators as suggested by Norman, Jr. and Grinnell et al '199.

4. Claims 1, 2, 7 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,193,681 (Davidner et al) in view of Norman, Jr. Davidner et al teach a hemofiltration method and system comprising a hemofilter (106) to remove selective inflammatory mediators including TNF, IL-1 beta from blood and connected to filter devices (111, 112) to remove inflammatory mediators including endotoxins (see col. 3, lines 8-36; col. 4, line 66 - col. 5, line 62; col. 7, lines 8-30). Davidner et al further teach that his hemofilter removes the inflammatory mediators including TNF, IL-1 beta that are removed by hemofilter of 100 kD - 150 kD of U.S. Patent No. 5,571,418 (Lee et al). Claims 1-2, 7 and 11 essentially differ from the hemofiltration method and system of Davidner et al in reciting the provision of therapeutic agent selected from the group consisting of allopurinol, elastase inhibitors and prostaglandin inhibitors. Norman, Jr. teaches that IL-1 and TNF as major mediators of the systemic response to diseases such as sepsis and pancreatitis and as activators of the remaining members of the cytokine cascade and activates inflammatory cytokines (see col. 4, line 40 – col. 5, line 22). Norman, Jr. further teaches that IL-1 block can be administered in combination with other drugs such as prostaglandin inhibitors (i.e., non-steroidal, anti-inflammatory drugs such as aspirin, indomethacin, ibuprofen, etc.) to inhibit IL-1 production (see col. 6, lines 34-63; col. 9, lines 27-50). It would have been obvious to a person of ordinary skill in the art to modify the hemofiltration system and method of Davidner et al to provide one therapeutic agent including prostaglandins inhibitors to effectively treat inflammation caused by inflammatory mediators as suggested by Norman, Jr.

5. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Davidner et al in view of Norman, Jr. and Grinnell et al '199. Davidner et al teach a hemofiltration system

comprising a hemofilter (106) to remove selective inflammatory mediators including TNF, IL-1 beta from blood and connected to filter devices (111, 112) to remove inflammatory mediators including endotoxins (see col. 3, lines 8-36; col. 4, line 66 - col. 5, line 62; col. 7, lines 8-30). Davidner et al further teach that his hemofilter removes the inflammatory mediators including TNF, IL-1 beta that are removed by hemofilter of 100 kD - 150 kD of U.S. Patent No. 5,571,418 (Lee et al). Claim 12 essentially differs from the hemofiltration method of Davidner et al in reciting the provision of therapeutic agent selected from the group consisting of allopurinol, elastase inhibitors and prostaglandin inhibitors and activated protein C. Norman, Jr. teaches that IL-1 and TNF as major mediators of the systemic response to diseases such as sepsis and pancreatitis and as activators of the remaining members of the cytokine cascade and activates inflammatory cytokines (see col. 4, line 40 – col. 5, line 22). Norman, Jr. further teaches that IL-1 block can be administered in combination with other drugs such as prostaglandin inhibitors (i.e., non-steroidal, anti-inflammatory drugs such as aspirin, indomethacin, ibuprofen, etc.) to inhibit IL-1 production (see col. 6, lines 34-63; col. 9, lines 27-50). Grinnell et al '199 teach that activated protein C is used to treat sepsis caused by inflammatory mediators because of its anti-inflammatory effects through its inhibition of cytokine generation (e.g. TNF and IL-1) (see abstract; col. 1, lines 41-53). It would have been obvious to a person of ordinary skill in the art to modify the hemofiltration method of Davidner et al to provide one therapeutic agent including prostaglandins inhibitors and activated protein C in blood to effectively treat inflammation caused by inflammatory mediators as suggested by Norman, Jr. and Grinnell et al '199.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Kim whose telephone number is (703) 308-2350. The examiner can normally be reached on weekdays from 7:00 AM - 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can be reached on (703) 308-0457. The fax phone number for official response after final action is (703) 872-9311, and the fax phone number for all other official faxes is (703) 872-9310.

When sending a draft amendment by fax, please mark the paper as "DRAFT"; otherwise, mark the paper "OFFICIAL". This will expedite the processing of the paper.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0651.

John Kim

John Kim
Primary Examiner
Art Unit 1723

J. Kim
August 5, 2003